

REMARKS

This response is submitted in reply to the Office Action from the United States Patent and Trademark Office, dated April 25, 2008 ("the Action"). Claims 1-24, 51-53 and 61-76 are pending in the application.

I. The Allowed/Allowable Claims

Applicants acknowledge, with appreciation, the Examiner's statements that Claims 12-14, 17, 52 and 53 are allowed and that Claims 5, 61, and 70-75 would be allowable if amended in independent form including the limitations of the base claim and any intervening claims. Claims 5, 61 and 70 have been amended accordingly. Claims 71-75 depend directly or indirectly from Claim 70. In view of the above, Applicant respectfully submits that Claims 5, 12-14, 17, 52, 53, 61 and 70-75 should be allowed.

II. The Art Rejections

The Action has withdrawn the allowance of Claims 1-11, 51 and 66 in view of a newly discovered reference, U.S. Patent No. 6,488,181 to Schuller et al ("Schuller"). The Action alleges that Schuller teaches the use of non-linear vibration input signals with selected frequencies corresponding to the flow characteristic frequencies. The Action also alleges that the device of Schuller will "perform the method of Claims 1-2" during normal operational use. The Action also disregards the small metered doses contemplated by some of the dependent claims, alleging that such is only "discovering optimal ranges". Applicant respectfully disagrees with these rejections.

Applicant agrees that Schuller teaches vibrating dry powder. However, Schuller fails to teach or suggest the claimed vibrational signal, *e.g.*, the first non-linear input signal comprising a carrier frequency modulated by a plurality of different selected frequencies that correspond to a first non-pharmaceutical dry powder formulation as recited in Claim 1. Instead, Schuller proposes using a metering base of plastic, metal or textile fabric of varying mesh width, wherein the mesh width is selected as a function of the material to be metered and of the desired metering accuracy and speed (col. 2, line 66 to col. 3, line 4).

Schuller goes on to state that, as a result of the oscillating bearing of the receiving vessel, "gentle vibration pulses" are delivered to the storage vessel during metering (col. 3, lines 51-56). The vibrational frequency of Schuller can be adjusted continuously from a low to a high frequency, from 0-180 Hz. (col. 3, lines 60-65). Thus, the signal can use different single frequencies from 0-180 Hz, but not a carrier frequency modulated by different selected frequencies. The gentle vibration pulses are not equivalent to the claimed input signal and Schuller does not perform the methods of Claims 1-2 "during normal use."

1. A method of flowably dispensing or processing dry powders from a device having a dry powder flow path, comprising:
generating a first non-linear vibration input signal, the first non-linear input signal comprising a carrier frequency modulated by a plurality of different selected frequencies that correspond to a first non-pharmaceutical dry powder formulation; and
applying the first non-linear vibration input signal to a portion of a dry powder flow path while the first dry powder formulation is flowing therethrough.

51. A system of flowably processing and/or dispensing non-pharmaceutical dry powders from a device having a dry powder flow path, comprising:
means for generating a first non-linear vibration input signal, the first non-linear input signal comprising a carrier frequency modulated by a plurality of different selected frequencies that correspond to flow frequencies in flow characteristics of a first non-pharmaceutical dry powder formulation; and
means for applying the first non-linear vibration input signal to a dispensing device having at least one dispensing port while the first dry powder formulation is flowing therethrough; and
means for dispensing a first quantity of the first dry powder.

66. A method of operating a dry powder filling system for dispensing non-pharmaceutical formulations of dry powder substances, comprising:
generating a vibratory signal comprising a carrier frequency modulated by a plurality of selected frequencies, wherein the selected frequencies corresponding to identified *a priori* flow characteristic frequencies of a non-pharmaceutical dry powder;

applying the generated vibratory signal to a dry powder in a dispensing flow path of a bulk powder enclosure; then dispensing metered quantities of the dry powder from the dispensing flow path during the applying step.

Thus, while the Action alleges that Schuller teaches using "different selected frequencies", a closer reading of Schuller reveals that Schuller uses a single frequency that may be varied or adjusted, not a signal with selected frequencies used simultaneously as claimed, *e.g.*, a carrier frequency modulated by the different selected frequencies. Clearly, Schuller fails to teach or suggest the claimed signal, including at least the features emphasized in the claims restated above. Accordingly, Applicant submits that Schuller fails to anticipate the claims.

The Action concedes that Schuller fails to teach certain of the features in certain of the dependent claims (*e.g.*, the recited frequency ranges 19-20, 68-69 or the modulating frequencies, Claim 65) but goes on to allege that those claims are obvious over Schuller, because, where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only "routine skill." The Action also alleges that the use of more than one modulating frequency (Claims 64-65) is merely a duplication of "essential parts" involving only routine skill. Applicant respectfully disagrees.

Applicant agrees that the use of vibration to dispense dry powders is known. However, the claimed vibratory signal is very different from the vibration frequency generated by the oscillating bearing of Schuller. Such is not merely discovering optimum or workable ranges or duplicating parts. The claimed devices and methods employ novel vibrational signals. Further, it is unclear how one of skill in the art would have modified the vibration of Schuller in a manner that would yield the instant invention absent the teachings of the instant invention.

Schuller vibrates the receiving vessel 3, which does not contact the hopper 2 directly. The hopper 2 and the receiving vessel are in communication via oscillating bearing 4, which causes "gentle vibration pulses" to be transmitted to the storage vessel 1 during metering (col. 3, lines 4-10, 26-32, 50-56). Schuller states that the vibration frequency of the drive can be adjusted "continuously" by means of a proportioning valve in the range of 0- 180 Hz. Again, the vibration signal has a single frequency that varies continuously. Further, Schuller fails to teach or suggest, *inter alia*, that the non-linear vibratory energy comprises a carrier frequency

modulated by a plurality of different selected modulating frequencies that correspond to a first dry powder formulation.

Applicant submits that the dependent claims recite features that are patentable over the cited prior art, *e.g.*, *see* Claims 3, 4, 6, 7, 1, 17, 20, 62-65, and 67-69. For example, Schuller teaches a frequency in the range of 0-180 Hz, which is clearly well below the carrier frequencies recited in Claim 20.

Applicant respectfully directs the Examiner's attention to the improvement in dispensing reflected by the graphs below and as previously discussed in the Response mailed August 30, 2007.

As discussed by Dr. Timothy Crowder (one of the inventors of the pending application) in *Precision powder metering utilizing fundamental powder flow characteristics*, Powder Technology 173 (2007) 217-223, experimental results using vibration frequencies calculated from physical characterization of the dry powders indicated that the vibratory signal with these frequencies "had a significant influence on the reproducibility of metering". (Abstract). *See also*, Figures 5 and 6 of this article provided hereinbelow for ease of reference, which demonstrate flow filling data comparing sinusoidal to powder specific vibration. The signal is turned on at between 36-45 seconds in Figure 5a making the mass flow rate relatively constant. Figure 5

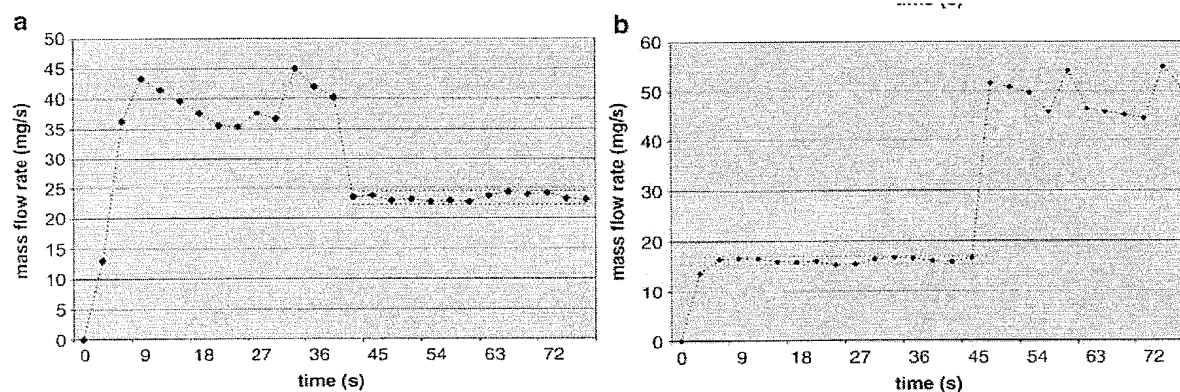
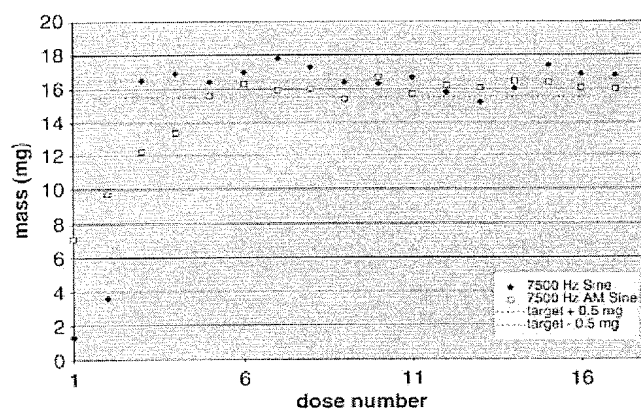


Figure 6



For a more complete discussion of the experimental data, Applicant respectfully directs the Examiner's attention to the article. Thus, Applicant respectfully submits that the claimed vibratory signal is non-obvious over prior art vibrations and clearly provides a more uniform fluidic flow, which can improve filling processes/systems.

III. Hindsight

Applicant directs the Examiner's attention to two recent decisions by the BPAI that have overturned an Examiner's obviousness rejections. In one case the BPAI stated that the Examiner used the unwitting application of hindsight, which is inappropriate. *Ex Parte So and Thomas*, BPAI 2007-3967 (Jan. 4, 2008). In another illustrative and recent case before the BPAI, an Examiner alleged that it would have been obvious to one of ordinary skill to optimize workable ranges of a claim. The BPAI reversed the Examiner, pointing out that optimization of a known result-effective variable is generally obvious only when it is reasonably expected that an improvement will arise in that range. See, *Ex parte Atkinson and Benedict*, BPAI Appeal No. 2007-3900 (December 18, 2007) (emphasis added). Applicant respectfully submits that the Action is incorrect when it alleges that the claimed invention would have been obvious based on the teachings of the instant application. Applicant submits that such an analysis employs "unwitting" hindsight.

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Filed: June 26, 2003
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IV. Terminal Disclaimer

Out of an abundance of caution, Applicant is also submitting a Terminal Disclaimer for co-pending, commonly owned, Application Serial No. 11/179163 (for which Applicant has received a Notice of Allowance). This application is a divisional application of U.S. 6,985,798 (for which Applicant has previously submitted a Terminal Disclaimer).

Also out of an abundance of caution, Applicant submits that the Examiner in U.S. Application Serial No. 11/043,363 ("the '363 application") directed to inhalers, required a Terminal Disclaimer with respect to U.S. Application Serial No. 11/179,163 (9336-3DV). Applicant does not believe that a Terminal Disclaimer is required for the '363 application but offers to provide one upon request.

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,



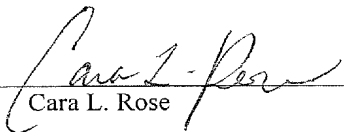
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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on July 14, 2008.

Signature: _____



Cara L. Rose